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10/033,101	10/19/2001	Robert E. Dudley	01917590	7711

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Joseph A. Mahoney
Mayer, Brown & Platt
P.O. Box 2828
Chicago, IL 60690-2828

EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/033,101

Applicant(s)

DUDLEY ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21,27,53-55,57,58,60-64 and 79-145 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21,27,53-55,57,58,60-64 and 79-145 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

DETAILED ACTION

This application is a divisional of Serial No. 09/651777 now patented 6,503,894.

Applicant's preliminary amendment in Paper No. 4, submitted April 5, 2002 wherein the instant application have been amended as to page 15-21, and Applicant's preliminary amendment in Paper No. 5, submitted May 2, 2002, wherein the instant application have been amended as to page 2, 8-10, 13, 22, 26, 34, 37-38, 48, 54, 59, 62, 65, 67, and 69, and claims 22-26, 28-52, 56, 59, and 65-78 are cancelled and claims 1-5, 27, 53-55, and 57, 58, 60-64, and 79 have been amended, and claims 80-145 are newly submitted, are acknowledged. Currently, claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "the profile shown in FIG.1(c) " in claim 7 renders the claim indefinite. Each claim must be self-contained. The expression "the profile shown in FIG.1(c) " is unclear as to the method encompassed thereby.

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The expressions "a steady-state" in claims 6-7, "relatively constant" in claim 8, and "increased ..." in claims 9-10, 12, and 16-17, and "improved" in claims 13-15 and 18-19, and "normal range" in claim 21, are relative terms which renders these claims indefinite. The scope of the claim is unclear as to what may be considered as "a steady-state", "relatively constant", "increased ...", "normal range", and "improved" herein.

Claims 6-10, 12-13, 15-16, 18 and 20 recite the limitation "the application". There is insufficient antecedent basis for this limitation in the claim since claim 1 is drawn to the method comprising a composition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-42 of U.S. Patent No. 6,503,894.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent are drawn to a method for administering a composition to skin of a human subject in need of thereof. The claim of the instant application is drawn to methods of transdermally delivering the same composition to a male subject. One having ordinary skill in the art at the time the invention was made would have been motivated to administer the same composition herein a method for administering a composition to skin of a human subject in need of thereof in the patent in to the claimed methods herein of transdermally delivering the same composition to a male subject since these methods between in the patent and in the instant application are seen to substantially overlap.

Thus, the instant claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 are seen to be obvious over the claims 18-42 of U.S. Patent No. 6,503,894.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 of copending Application No. 09/703,753.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application are drawn to methods for for improving the efficacy of a pharmaceutical comprising percutaneously administering a composition to a male subject. The claim of the instant application is drawn to methods of transdermally delivering the same composition to a male subject. One having ordinary skill in the art at the time the invention was made would have been motivated to administer the same composition herein a method for administering a composition to skin of a human subject in need of thereof in the patent in to the claimed methods herein of transdermally delivering the same composition to a male subject since these methods between in the copending application and in the instant application are seen to substantially overlap.

Thus, the instant claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 are seen to be obvious over the claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 of copending Application No. 09/703,753.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (WO 99/24041, of record in the parent application 09/651, 777) and Heiber et al. (WO 93/25168, of record in the parent application 09/651, 777), and Omar (5,730,987, of record in the parent application 09/651, 777) and Moreland et al. (of record in the parent application 09/651, 777) in view of Allen (WO 96/227372, of record in the parent application 09/651, 777).

Mak et al. discloses an enhancement of the penetration of transdermally (percutaneously) or topically applied a pharmaceutical composition comprising an active agent, testosterone, and a penetration-enhancing system that comprises oleic acid (a fatty acid having 17 carbon atoms), C1-C4 alcohol (e.g., ethanol, 2-propanol), and the gelling agent (a thickener), CARBOPOL (a polyacrylic acid). See abstract, page 3 lines 1-5, page 10 Example 1, and Figure 2.

Heiber et al. (WO 93/25168) discloses that testosterone compositions comprising a transdermal (percutaneous) delivery system comprising C2 or C3 alcohol, a penetration enhancer therein, i.e., glycerine, and a gelling agent, are useful in methods moderating and maintaining transdermal drug delivery to the derma at a relatively

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sustained rate over the duration of application to situs. See abstract, Example 3 at page 19-21, and claims 1-46 and 48.

Omar discloses that the particular steroid, testosterone and yohimbine HCl (ACTIBINE) or a combination thereof to be administered are useful in the composition and the method of the treatment of impotent in human males, i.e., erectile dysfunction. See col.1 lines 17-62 and claims 6-8.

Moreland et al. teaches that the phosphodiesterase type 5 inhibitor, sildenafil, is useful in the treatment of male erectile dysfunction. See Abstract and Introduction.

The prior art does not expressly disclose a method for improving the efficacy of a pharmaceutical useful for treating erectile dysfunction in a male who may be an eugonadal comprising the particular steroid, testosterone, C1-C4 alcohol, and the particular penetration enhancer, isopropyl myristate, and the effective amounts of active ingredients in the composition.

Allen discloses a topical cream composition useful for treating male erectile dysfunction comprising the particular penetration enhancer, isopropyl myristate or glycerine. See abstract and claim 1 and 4.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular steroid, testosterone, C1-C4 alcohol, and the particular penetration enhancer, C8-C22 fatty acid and isopropyl myristate in a method for improving the efficacy of the composition herein useful for treating erectile dysfunction in a male who may be an eugonadal, and to further add the

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phosphodiesterase type 5 inhibitor, sildenafil or yohimbine HCl to the composition, and optimize the effective amounts of active ingredients in the composition.

One having ordinary skill in the art would have been motivated to employ the particular steroid, testosterone, C1-C4 alcohol, and the particular penetration enhancer, C8-C22 fatty acid and isopropyl myristate in a method for improving the efficacy of the composition herein useful for treating erectile dysfunction in an eugonadal male since the composition containing testosterone of Mak et al. is known to be useful in a method for improving the efficacy of percutaneously delivering a pharmaceutical because this composition further comprises a transdermally or topically penetration-enhancing system encompassing an oleic acid (a fatty acid having 17 carbon atoms), C1-C4 alcohol (e.g., ethanol, 2-propanol), and a penetration enhancer and a gelling agent. Moreover, the teachings of Heiber et al. have further provided the motivation to make the present invention since testosterone compositions of Heiber are known to comprise a transdermal (percutaneous) delivery system comprising C2 or C3 alcohol, a penetration enhancer therein, i.e., glycerine, and a gelling agent, and these compositions are known to be useful in methods moderating and maintaining transdermal drug delivery to the derma at a relatively sustained rate over the duration of application to situs.

The particular steroid, testosterone, is well known to be useful to treat erectile dysfunction in a male according to Omar. It is also well known that an eugonadal male suffers erectile dysfunction. Therefore, one of ordinary skill in the art would have found it obvious to employ the composition of Mak et al. in the instant claimed method. The

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topical cream composition of Allen is also known to be useful for treating male erectile dysfunction comprising the particular penetration enhancer herein, isopropyl myristate, which provides additional motivation for the claimed method.

One of ordinary skill in the art would also have been motivated to add the phosphodiesterase type 5 inhibitor, sildenafil or yohimbine HCl to the composition since the combination of testosterone and yohimbine HCl or yohimbine HCl alone or sildenafil are all known to be useful in the treatment of male erectile dysfunction according to Omar and Moreland. Therefore, one of ordinary skill in the art would have reasonably expected that adding yohimbine HCl or sildenafil to Mak's composition would improve the therapeutic effect of Mak's composition to treat male erectile dysfunction.

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of amounts of active agents to be administered is considered well within the skill of artisan.

Since all composition components herein are known to be useful to treat male erectile dysfunction, it is considered *prima facie* obvious to combine them into a single composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

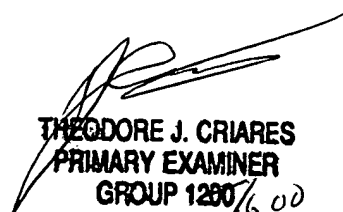
In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. A. Jiang, Ph.D.
Patent Examiner, AU 1617
January 8, 2003



THEODORE J. CRIARES
PRIMARY EXAMINER
GROUP 1200/6 00